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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/821,025	03/19/1997	HENDRIK LOUIS BIJL	246152006900	3574
25225	7590	12/29/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			MARX, IRENE	
		ART UNIT		PAPER NUMBER
				1651

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	08/821,025	BIJL ET AL.
	Examiner	Art Unit
	Irene Marx	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 November 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 68-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 68-95 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

The amendment filed 11/5/04 is acknowledged. Claims 68-95 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is vague and indefinite in that the period of stability cannot be readily assessed. the terminology "for weeks" is ambiguous and open to interpretation.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) d potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68-95 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay taken with Carduck *et al.*, Akimoto *et al.*, Casey *et al.* and Remington *et al.* for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant appears to argue that "consisting essentially of" should be interpreted in this case that the fungi or bacteria have all been extruded into granule form, though one or two may have escaped at some point. However, it is the position of the Examiner that the transitional

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phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz* , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.* , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.* , 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)(“Although ‘consisting essentially of’ is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification [I]t is an applicant’s burden to establish that a step practiced in a prior art method is excluded from his claims by ‘consisting essentially of’ language.”).

Herein applicant has not demonstrated that the presence of dry ground grain material in affects the basic and novel characteristics of the composition. In Barclay, for example, the cells are mixed with a dry ground grain, such as corn, which is deemed to be an inert additive, to produce a microbial extruded product (See, e.g., Example 14, particularly col. 33, lines 1-5). This extruded microbial product can reasonably be presumed to be stable for “weeks”. Even

though Barclay is silent as to the size range of the extrudate granules and their porosity parameters, the dried microbial extruded product of Carduck consists essentially of porous granules containing fungi produced by extrusion having the correct dimensions and is storage stable for "commercially acceptable periods" (col. 7, lines 15-17). In addition, Applicant has not demonstrated with objective evidence that the properties of the granules of Carduck in the context of the instant invention are substantially altered whether the yeasts therein are dead or alive. The only difference between the stable product of Carduck and the claimed product is that the microorganisms are active as opposed to dead. For the intended extraction purpose this property is not deemed material.

Applicant's argument that the cited "publications" are not well known is puzzling and not well taken, since both documents are U.S. patents.

One of ordinary skill in this art would have had compelling motivation to substitute fungi or bacteria taught by Akimoto *et al.* or Casey *et al.* known to produce valuable biopharmaceutical products in the extruded compositions of Barclay and Carduck which are stable "for weeks" and comprise porous granules of a diameter between 0.1 and 12 mm for the expected benefit of providing a storage stable granular product containing extractable commercially valuable pharmaceutical products.

Contrary to applicants contentions at page 10 of the response, the product of Carduck is stable on storage for weeks even though the fungi or bacteria therein are alive rather than dead, and this product does have the required diameter range. The limitation that it is known in the art to provide an extruded granular composition containing cells that "are dead and non-disrupted" is adequately provided by Barclay. Moreover, the specific process of attaining the touted "porosity" of the composition has not been shown to materially alter the properties of the composition as claimed. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Applicant's arguments have failed to rebut the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651